

What is claimed is:

Sub 17 1. A catheter for use in conveyance of a formulation, the catheter comprising:  
first and second materials configured to define a tubular structure, the tubular structure  
having a proximal and a distal end;

5 wherein the second material has a permeability lower than polyethylene for at least one  
substance that could cause detrimental change in the properties or composition of the  
formulation.

10 2. The catheter as recited in claim 1, wherein the first material is disposed outside the  
second material.

15 3. The catheter as recited in claim 1, wherein the first material is disposed inside the  
second material.

4. The catheter as recited in claim 1, wherein the second material comprises a material  
that has a permeability index for the at least one substance that is lower than the permeability  
index of the outer material for the at least one substance.

20 5. The catheter as recited in claim 4, wherein the at least one substance comprises CO<sub>2</sub>  
and wherein the detrimental change occurs as a result of diffusion of the CO<sub>2</sub> into the catheter.

6. The catheter as recited in claim 4, wherein the at least one substance comprises phenolic compounds and wherein the detrimental change occurs as a result of diffusion of the phenolic compounds out of the catheter.

5 7. The catheter as recited in claim 6, wherein the phenolic compounds comprise at least one of phenol and m-cresol.

8. The catheter as recited in claim 1, wherein the second material comprises a material selected from the group consisting of halogenated polymers.

9. The catheter as recited in claim 8, wherein the halogenated polymer is selected from the group essentially consisting of polytetrafluorethylene, polyvinylidene chloride and polyvinylidene fluoride.

10. The catheter as recited in claim 1, wherein the second material comprises a material selected from the group consisting essentially of polyamides, ethylene-vinyl alcohol, polyetheretherketone, nylon and polyester.

11. The catheter as recited in claim 1, wherein the second material is capillary glass.

12. The catheter as recited in claim 1, wherein the second material is diamond coated.

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14. The catheter as recited in claim 2, wherein an inner surface of the first material substantially covers an outer surface of the second material.

16. The catheter as recited in claim 15, wherein the portion of the outer surface of the second material covered by the inner surface of the first material is located at the distal end.

18. The catheter as recited in claim 17, wherein the substance is a hydrophilic substance.

19. The catheter as recited in claim 17, wherein the substance is a hydrophobic substance.

20. The catheter as recited in claim 1, wherein an inner diameter of the distal end has a flared shape.

21. The catheter as recited in claim 20, wherein an outer diameter of the distal end is substantially constant across the flared shape.

22. The catheter as recited in claim 1, wherein the proximal end is connected to an implantable infusion pump.

23. The catheter as recited in claim 1, wherein the first material is more flexible than the second material.

24. The catheter as recited in claim 1, wherein the first material has a lower flexural modulus than the second material.

25. A catheter for use in delivery of a formulation, the catheter comprising:  
an outer layer comprising an outer surface and an inner surface;  
a barrier layer comprising an outer surface and an inner surface;  
a proximal end; and  
a distal end having a surface on which an obstruction may form;  
wherein the barrier layer further comprises flowholes formed therein at a sufficient upstream distance from any obstruction formed at the distal end, the flowholes providing entry into an annular channel located on the downstream side of the flowholes, the annular channel being bounded by a portion of the inner surface of the outer layer and a portion of the outer surface of the barrier layer, the annular channel providing a passageway out of the catheter for the formulation in the event of an obstruction, the portion of the inner surface of the outer

layer, under sufficient pressure, elastically separating from the portion of the outer surface of the barrier layer to complete the passageway.

26. The catheter as recited in claim 25, wherein the inner surface of the outer layer  
5 substantially covers the outer surface of the barrier layer.

27. The catheter as recited in claim 25, wherein the inner surface of the outer layer covers  
only a portion of the outer surface of the barrier layer.

28. The catheter as recited in claim 27, wherein the portion of the outer surface of the  
barrier layer covered by the inner surface of the outer layer is located at the distal end.

29. The catheter as recited in claim 25, wherein an inner diameter of the distal end has a  
flared shape.

30. The catheter as recited in claim 29, wherein an outer diameter of the distal end is  
substantially constant across the flared shape.

31. A catheter for use in delivery of a formulation, the catheter comprising:  
20 an outer layer comprising an outer surface and an inner surface, a portion of the outer  
surface further comprising an annular plug having an outer surface and an inner surface;  
a barrier layer comprising an outer surface and an inner surface;  
a proximal end; and

a distal end having a surface on which an obstruction may form;

wherein the barrier layer and the outer layer further comprise flowholes formed jointly therein at a sufficient upstream distance from any obstruction formed at the distal end, the flowholes providing entry into an annular channel located on the downstream side of the flowholes, the annular channel being bounded by a portion of the inner surface of the annular plug and a portion of the outer surface of the outer layer, the annular channel providing a passageway out of the catheter for the formulation in the event of an obstruction, the portion of the inner surface of the annular plug, under sufficient pressure, elastically separating from the portion of the outer surface of the outer layer to complete the passageway.

32. The catheter as recited in claim 31, wherein the annular plug comprises a material that is bio-compatible.

33. The catheter as recited in claim 31, wherein the inner surface of the outer layer substantially covers the outer surface of the barrier layer.

34. The catheter as recited in claim 31, wherein the inner surface of the outer layer covers only a portion of the outer surface of the barrier layer.

35. The catheter as recited in claim 31, wherein the portion of the outer surface of the barrier layer covered by the inner surface of the outer layer is located at the distal end.

36. The catheter as recited in claim 31, wherein an inner diameter of the distal end has a flared shape.

37. The catheter as recited in claim 36, wherein an outer diameter of the distal end is substantially constant across the flared shape.

38. A catheter for use in conveyance of a formulation, the catheter comprising:  
an outer material;  
an inner barrier material;  
a proximal end; and  
a distal end;  
wherein the outer material protrudes a distance beyond the inner barrier material at the distal end and forms a generally semi spherical segment spaced from and enclosing the distal end, the semi spherical segment comprising at least one slit formed thereon, the at least one slit expanding upon a pump stroke of an infusion pump to release the formulation and closing at an interval between pump strokes to hinder inflow of substances into the distal end of the catheter.

39. The catheter as recited in claim 38, wherein the inner surface of the outer material substantially covers the outer surface of the inner barrier material.

40. The catheter as recited in claim 38, wherein the inner surface of the outer material covers only a portion of the outer surface of the inner barrier material.

41. The catheter as recited in claim 40, wherein the portion of the outer surface of the inner barrier material covered by the inner surface of the outer material is located at the distal end.

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42. The catheter as recited in claim 38, wherein an inner diameter of the distal end has a flared shape.

43. The catheter as recited in claim 42, wherein an outer diameter of the distal end is substantially constant across the flared shape.

44. An implantable infusion pump system for use in delivery of a formulation, the system comprising:

a pump for delivering measured doses of a formulation;

a sensing device for regulating the delivery of the formulation; and

a catheter for conveying the formulation from the pump to an infusion site, the catheter comprising:

an outer material;

an inner barrier material;

a proximal end attached to the pump; and

a distal end located at the infusion site;

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wherein the barrier material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of the formulation.

5 45. An implantable infusion pump system for use in delivery of a formulation, the system comprising:

a pump for delivering measured doses of a formulation;

a sensing device for regulating the delivery of the formulation; and

a catheter for conveying the formulation from the pump to an infusion site, the catheter

comprising:

an outer layer comprising an outer surface and an inner surface;

a barrier layer comprising an outer surface and an inner surface;

a proximal end attached to the pump; and,

a distal end located at the infusion site, the distal end having a surface on which

an obstruction may form;

wherein the barrier layer further comprises flowholes formed therein at a sufficient upstream distance from any obstruction formed at the distal end, the flowholes providing entry into an annular channel located on the downstream side of the flowholes, the annular channel being bounded by a portion of the inner surface of the outer layer and a portion of the outer surface of the barrier layer, the annular channel providing a passageway out of the catheter for the formulation in the event of an obstruction, the portion of the inner surface of the outer layer, under sufficient

pressure, elastically separating from the portion of the outer surface of the barrier layer to complete the passageway.

46. An implantable infusion pump system for use in delivery of a formulation, the system  
5 comprising:

a pump for delivering measured doses of a formulation;

a sensing device for regulating the delivery of the formulation; and

a catheter for conveying the formulation from the pump to an infusion site, the catheter

comprising:

an outer layer comprising an outer surface and an inner surface, a portion of the  
outer surface further comprising an annular plug having an outer surface and an inner surface;

a barrier layer comprising an outer surface and an inner surface;

a proximal end; and

a distal end having a surface on which an obstruction may form;

wherein the barrier layer and the outer layer further comprise flowholes formed  
jointly therein at a sufficient upstream distance from any obstruction formed at the  
distal end, the flowholes providing entry into an annular channel located on the  
downstream side of the flowholes, the annular channel being bounded by a portion of  
the inner surface of the annular plug and a portion of the outer surface of the outer  
layer, the annular channel providing a passageway out of the catheter for the  
formulation in the event of an obstruction, the portion of the inner surface of the  
annular plug, under sufficient pressure, elastically separating from the portion of the  
outer surface of the outer layer to complete the passageway.

47. An implantable infusion pump system for use in delivery of a formulation, the system comprising:

a pump for delivering measured doses of a formulation;

5 a sensing device for regulating the delivery of the formulation; and

a catheter for conveying the formulation from the pump to an infusion site, the catheter comprising:

a proximal end attached to the pump; and

a distal end located at the infusion site;

wherein the catheter comprises a material having a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of the formulation.

48. The implantable infusion pump system as recited in claim 47, wherein the material comprises a material selected from the group consisting of halogenated polymers.

49. The implantable infusion pump system as recited in claim 48, wherein the halogenated polymer is selected from the group essentially consisting of polytetrafluorethylene, polyvinylidene chloride and polyvinylidene fluoride.

20 50. The implantable infusion pump system as recited in claim 47, wherein the material comprises a material selected from the group consisting essentially of polyamides, ethylene-vinyl alcohol, polyetheretherketone, nylon and polyester.

51. The implantable infusion pump system as recited in claim 47, wherein the material is capillary glass.

5 52. The implantable infusion pump system as recited in claim 47, wherein the material is a diamond coated material.

53. A catheter for use in conveyance of a formulation, the catheter comprising:

an outer material;

an inner material;

a proximal end; and

a distal end;

wherein at least one of the outer material and the inner material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of the formulation.

54. A catheter for use in delivery of a formulation, the catheter comprising:

an outer layer comprising an outer surface and an inner surface;

a barrier layer comprising an outer surface and an inner surface;

a proximal end; and

a distal end;

wherein the inner surface of the outer layer covers the outer surface of the barrier layer only at the distal end of the catheter.